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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,356	03/31/2004	Mark S. Zeiner	END-5008CIP2	8274

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PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER

YABUT, DIANE D

ART UNIT	PAPER NUMBER
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3734

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/815,356	Applicant(s) ZEINER, MARK S.	
	Examiner Diane Yabut	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. There was no information disclosure statement filed and application fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. An information disclosure statement form PTO-1449 must be submitted.

Specification

2. The disclosure is objected to because of the following informalities:
On page 6, paragraph 24 it reads "gasket ring 20" and should instead read --gasket ring 8--. On page 8, paragraph 28 and page 9, paragraph 31, "non-planer" should be changed to --non-planar--. On page 8, paragraph 30, it reads "one can use only four pins are for" and should instead read --one can use only four pins for-- and it also reads "be located the gasket ring" and should be changed to --be located on the gasket ring--. On page 10, paragraph 33, "Figure 5 shows" should be changed to --Figure 4 shows--. On page 11, paragraph 36 it reads "to maintain insulflation" and should rather read --to

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maintain insulation-- and it also reads "no hole present provides" and should be changed to --no hole present providing--. Lastly, on page 12, paragraph 38 it reads "plurality of protrusions 302" and should instead be --plurality of protrusions 202-- and it also reads "proximal surface 111" and should instead be --proximal surface 211--.

Appropriate correction is required.

3. The preliminary amendment to specification is objected to because of the following informalities. Note: Pages 2 and 3 were on file.

On page 2, deleting paragraph 2 would delete "Field of the Invention," which is unnecessary. Deleting paragraph 18 would delete the brief description for Figure 8, which would also be unnecessary. Also, amending paragraph 19 would add to the brief description of Figure 9, and should instead be for amending paragraph 17, which is the description for Figure 7, the cross-sectional view of trocar 100 ("Figure 6" should instead be --Figure 7--). On page 3, in reference to paragraph 27, "gasket pin holes 26" should be changed to --gasket pin holes 28--.

Drawings

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference signs mentioned in the description: On page 5, paragraph 21: "obturator portion **120**" and "piercing tip **122**." Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the

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filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

5. Claims 4,8,10,16, and 24 are objected to because of the following informalities:

Claim 4: "The trocar according to claim 4" should instead be --The trocar according to claim 3--, assuming Claim 4 is dependent on its previous claim.

Appropriate correction is required.

Claims 8,16, and 24: The term "non-planer" should be changed to --non-planar--.

Claim 10: "The trocar according to claim 10" should instead be --The trocar according to claim 9--, assuming Claim 10 is dependent on its previous claim.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 1,5,6,7,9,13-15,17 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hart et al.** (U.S. Patent No. **5,385,553**) in view of **Chin** (U.S. Patent No. **6,610,031**) and further in view of **Danks et al.** (U.S. Patent No. **5,364,372**) and

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Antoon, Jr. et al. (U.S. Patent No. **5,628,732**).

Claims 1, 9, and 17: Hart discloses a trocar **10** with a cannula **22** having an access (“hollow”) channel **24** with a distal end and proximal end and a valve housing **28** attached to the proximal end of the cannula, wherein the proximal end has a wall with an aperture through which instrument **26** is inserted (Figures 1-3). Hart discloses the claimed device except for the seal assembly comprising a first and second substantially rigid ring and a plurality of layered elastomeric members compressed therebetween with first and second rings having distally and proximally extending protrusions, respectively. Chin discloses a valve assembly with compression members **140** (“first substantially rigid ring”) and **141** (“second substantially rigid ring”) (Figure 1, col. 4, lines 10-12). Also disclosed is a plurality of layered elastomeric members **132** compressed between the first and second rings (Figure 1, col. 3, lines 34-35 and 60-63). Chin teaches that the configuration of the rings and members provide compression and support so that the surface of the elastomeric members are compressed toward the open portion of their adjacent members so that no continuous unoccupied opening or channel is present, thus retaining sealable control (Figures 3-4, col. 6, lines 52-65). It would have been obvious to one of ordinary skill in the art at the time of invention to add a seal assembly with a plurality of layered elastomeric members, as taught by Chin, to the device of Hart et al. in order to maintain sealable control of the valve assembly.

Antoon, Jr. et al. also discloses a seal with a ring with distal prongs **40** (“protrusions”) extending from a distal surface (Figure 3). Danks et al. discloses a membrane seal for a cannula that has a ring-shaped base with proximal mounting posts **99** (“protrusions”)

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extending from a proximal surface (Figure 9). Although the distally and proximally extending protrusions for both first and second rings are not in Antoon, Jr. et al. and Danks et al., it would have been obvious to one of ordinary skill in the art to add protrusions to one of either the rings or both since it was known in the art that there can be protrusions on either or both of two connecting elements.

Claims 5,13, and 21: Hart discloses a plurality of seal protectors that comprises outer leaves **105** and **107** and inner leaves **125** and **127** (Figures 9-10, col. 6, lines 48-68).

Claim 6,14, and 22: Chin discloses layered elastomeric members having a substantially centrally located aperture **137** in the seal assembly (Figures 3-4).

Claim 7,15, and 23: Chin discloses layered elastomeric members that are "woven" or combined together (Figures 3-4), according to its definition in The American Heritage® Dictionary of the English Language: Fourth Edition: the past participle of weave, or "to interweave or combine (elements) into a complex whole."

8. Claims 2-4,8,10-12,16,18-20, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hart et al.**, **Chin**, **Antoon, Jr. et al.**, and **Danks et al.** as applied to Claims 1, 9, and 17 above, and further in view of **Honkanen et al.** (U.S. Patent No. **4,655,752**).

Claims 2,10, and 18: Hart et al., Chin, Antoon, Jr. et al, and Danks et al. disclose the claimed device except for the plurality of elastomeric members forming a conical shape. Honkanen et al. discloses a cannula with a conically-shaped seal **55** (Figure 4). Honkanen et al. teaches that the conical shape assists in the formation of a tight seal about the instrument being inserted since fluid pressure will cause the conical seal

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member to collapse into the instrument and make it adhere more securely thereto (col. 4, lines 53-58). It would have been obvious to one skilled in the art to incorporate a conical shape to the plurality of elastomeric members as taught by Honkanen et al. to the combined device of Hart et al., Chin, Antoon, Jr. et al., and Danks et al., in order to assist in a more secure adhesion to the inserted instrument.

Claims 3,11, and 19: Honkanen et al. teaches the conical shape seal (see explanation for Claims 2,10, and 18 above), which has a proximal flange portion **56** and an inwardly extending conical portion **58** (Figure 2), which would be disposed between and are abutting against the rings in the device of Chin.

Claims 4,12, and 20: Hart et al. teaches a floating outer portion **39** (Figure 12, col. 2, lines 6-18) which is disposed around the seal assembly of Chin.

Claims 8,16, and 24: Honkanen et al. teaches the conical shape seal (see explanation for Claims 2,10, and 18 above), and when combined with the seal assembly of Chin, the plurality of elastomeric layers have a non-planar shape prior to being assembled.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. **Buess et al.**, U.S. Patent No. **5,800,451** disclosing a trocar system with layered sealing discs, and **Hasson et al.**, U.S. Patent No. **5,743,884** disclosing a sealing structure with multiple sealing members.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DY

GARY JACKSON
PRIMARY EXAMINER
GROUP 3300

